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Department of Veterans Affairs
Memorandum
VA Pittsburgh Healthcare System
Pittsburgh, PA

EXPEDITED REVIEW OF RESEARCH PROTOCOLS BY THE SUBCOMMITTEE FOR RESEARCH SAFETY/BIOSAFETY (SRS)

I. PURPOSE

Establish guidelines and procedures for the expedited review of protocols submitted to the Subcommittee for Research Safety/Biosafety (SRS).

II. POLICY

The laboratory procedures and practices included in Research protocols are reviewed by the SRS to insure compliance with policies and procedures of the VA Pittsburgh Healthcare System (VAPHS), the Occupational Safety & Health Administration (OSHA), the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC). There are circumstances where expedited review of protocols is appropriate, and will not require review by the full SRS. This policy provides a description of the procedure for such an expedited review.

III. PROCEDURE:

A. The Research Office receives Part II of the "Request to Conduct Research" form which is entitled "Part II: Research Safety/Biosafety Subcommittee Protocol Survey". This form is submitted to the SRS for

full committee review if the research involves one or more of the following: 1) biological hazards, 2) animal or human blood, body fluids, organs, tissues, cell lines or cell clones, 3) recombinant DNA, 4) chemicals, 5) controlled substances, and/or 6) ionizing or non-ionizing radiation.

B. Expedited initial review of a Research protocol can be approved by the subcommittee Chair when the following conditions are met:

    1. All answers on the "Part II: Research Safety/Biosafety Subcommittee Protocol Survey" are negative/not applicable.

    2. **If the protocol is a clinical study that involves the collection of human body fluids or tissues collected exclusively by clinical/pathology personnel.**

Notification of the approval will be communicated to the full Committee at the following meeting.

C. Expedited continuing review and study closures of a Research protocol can be approved by the subcommittee Chair when the following conditions are met:

    1. Animal care and use has been in accord with the approved protocol.

    2. The project has not changed since the last report with respect to the need for space, the need for equipment and supplies, and/or the personnel involved.

    3. No possible conflict of interest issues concerning the project have been identified.

    4. **The only change in the protocol is the source of funding.**

Notification of the approval will be communicated to the full Committee at the following meeting.

In the case of study closure, the Research Office will notify the Chemical and Radiation Safety Officers of the study closure when the protocols involved the use of chemicals and/or radiation. These safety officers will document and/or certify the proper storage or disposal of these research materials.

D. Expedited review of Amendments may be approved by the Chair as long as there is no significant change in exposure or handling of one or more of the following: 1) biological hazards, 2) animal or human blood, body fluids, organs, tissues, cell lines or cell clones, 3) recombinant DNA, 4) chemicals, 5) controlled substances, and/or 6) ionizing or non-ionizing radiation. A significant change would involve a change in the hazard level such that the safety of personnel would be affected in a manner greater than in the initial protocol.

IV. RESPONSIBILITIES

A. The Subcommittee for Research Safety/Biosafety is responsible for review of Research protocols and to insure that investigators adhere to the recommended safety policies and procedures.

V. REFERENCES

1. Subcommittee on Research Safety/Biosafety minutes. April 22, 2004 and October 9, 2003.

2. VA Pittsburgh Healthcare System IRB Policy. Section 6: IRB Record Keeping and Required Documentation.